DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 27, 2014

20/20 Imaging
% Daniel Kamm, P.E.
Principal Engineer
8870 Ravello Ct.
Naples, Florida 34114

Re: K141435
Trade/Device Name: Opal Chiro, 20/20 P-DR
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-ray System
Regulatory Class: Class II
Product Code: MQB
Dated: May 28, 2014
Received: May 30, 2014

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K141435

Device Name
Opal Chiro and 20/20 P-DR

Indications for Use *(Describe)*
Opal Chiro and 20/20 P-DR are intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
510(k) Number K141435

20/20 Imaging
2217 U.S. Highway 70 East
Garner, NC 27529
Phone: 866.734.6234
Fax: 919.772.2810
Date Prepared: July 30, 2014
Contact: Bruce Ashby, Sales and Marketing Manager

1. **Identification of the Device:**
   Proprietary-Trade Name: Opal Chiro and 20/20 P-DR Flat Panel X-Ray Detector upgrade kits.
   Classification Name: Stationary X-ray System, Product Code MQB, Regulation 892.1680
   Common/Usual Name: Digital X-Ray Receptor Panel

2. **Equivalent legally marketed devices**: K123644, Vizion +DR, Viztek LLC.

3. **Indications for Use (intended use)** Opal Chiro and 20/20 P-DR are intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography.

4. **Description of the Device**: The Opal Chiro and 20/20 P-DR system represents the straightforward integration of a new digital x-ray receptor panel (cleared in K062376) and our previously cleared (K123644 and K133139) software. The Opal Chiro and 20/20 P-DR are Digital Radiography systems, featuring an integrated flat panel digital detector (FPD). The Opal Chiro and 20/20 P-DR is designed to perform digital radiographic examinations as a replacement for conventional film. This integrated platform provides the benefits of PACS with the advantages of digital radiography for a filmless environment and improves cost effectiveness. The major functions and principle of operation of the Viztek PACS and the new receptor panel were not changed. Our main predicate is ViZion + DR, K123644, wherein we combined our OPAL-RAD software with two new digital panels. The upgrade kits are compatible with modern HF diagnostic X-ray generators like Sedecal and CPI. The 20/20 P-DR has been tested with X-Cel 700/900 series of generators.

5. **Safety and Effectiveness, comparison to predicate device**. The results of clinical image inspection, bench, and test laboratory results indicates that the new device is as safe and effective as the predicate devices. Clinical images collected demonstrate equal or better image quality as compared to our predicates.

6. **Substantial Equivalence Chart**

Characteristic	ViZion + DR, K123644	Opal Chiro and 20/20 P-DR
Intended Use:	ViZion + DR is intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. ViZion + allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities	Opal Chiro, model 20/20 C-DR and 20/20 P-DR are intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography.
Configuration	This submission is for the Digital Panel and Software only, no generator or stand provided.	This submission is for the Digital Panel and Software only, no generator or stand provided.

Characteristic	ViZion + DR, K123644	Opal Chiro and 20/20 P-DR
Digital Panel Sizes	iRay Technology (Shanghai) Ltd. For the 17" x 17" panel or 14" x 17" panel	The 17" x 17" panel stays the same. The 14" x 17" panel becomes a Naomi model. A smaller size of 10" x 12" is added for podiatry applications.
Digital panel resolutions	17" x 17" Pixel size 139 µm 3064×3072 pixels 14" x 17" Pixel size 150 µm 2288×2800 pixels	14" x 17" Pixel pitch: Horiz. 7.2 µm x Vert. 5.6 µm 7,872 x 6,144 (48.36 megapixels) 10" x 12" Horiz. 7.2 µm x Vert. 5.6 µm 4608 x 5904 (27.2 megapixels)
Software	OpalRad Software, outputs a DICOM image.	SAME
DICOM	Yes	Yes
Power source	AC Line	AC Line
Electrical safety and EMC	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2.	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2.

7. Summary of Bench Testing Conducted: The included products have been separately cleared by FDA and are provided to the user unmodified. Verification of operation has been performed via clinical image acquisition and review. See the paragraph below.

8. Summary of Clinical Testing: Clinical images were acquired and evaluated by a board certified radiologist who concluded the images from the new panel are as good as the images acquired with the predicate panel.

9. Conclusion: After analyzing bench, clinical image, and external laboratory testing to applicable standards, it is the conclusion of 20/20 Imaging that the Opal Chiro and 20/20 P-DR are as safe and effective as the predicate device, have few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.